NeuroMuscular Consultants

A Medical Corporation

411 - 30th Street, Suite 508, Oakland, CA 94609

(510) 832-5496 (phone) (510) 832-5498 (fax)

www.nmcdocs.com

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Tuesday
November 30, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 97N-484F

Dear Sir or Madam:

I write you in regard to the proposed FDA regulation which could allow the FDA to regulate some types of allograft as medical devices. I am fearful that such regulations, if imposed, will require bone banks to satisfy FDA pre-market requirements, such as sponsoring clinical trials and submitting lengthy regulatory documents. These we are clearly in no position to provide, and such regulation will predictably lead to a curtailed supply of bone products. We rely on such products for treating patients and the potential implications of FDA regulatory action are frightening.

I would urge you to not accept the aforementioned proposed regulation.

Should you have any further comments or questions, please do not hesitate to contact me at the above address and telephone number.

Sincerely,

Stephen Dell, M.D.
Neurosurgeon

SD:blp

97N 484S C261

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Neuro Muscular Consultants
A Medical Corporation
411 30th Street # 508
Oakland, CA 94609
888-832-5496

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